

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**

EXELA PHARMA SCIENCES, LLC;  
EXELA PHARMSCI, INC; and  
EXELA HOLDINGS, INC.

Plaintiffs,

vs.

HON. DAVID J. KAPPOS,  
Under Secretary of Commerce for Intellectual  
Property and Director of the United States  
Patent and Trademark Office and UNITED  
STATES PATENT AND TRADEMARK  
OFFICE;

Defendants,

and

SCR PHARMATOP and CADENCE  
PHARMACEUTICALS, INC.

Intervenors-Defendants.

Civil Action No. 1:12-cv-00469

**PLAINTIFF'S MEMORANDUM IN SUPPORT OF  
MOTION FOR SUMMARY JUDGMENT**

<i>Of counsel</i> Satish Chintapalli EXELA PHARMA SCIENCES, LLC 1325 William White Pl, NE Lenoir, NC 28645 828-758-5474 (telephone) 828-757-7888 (fax) <a href="mailto:satish@exela.us">satish@exela.us</a>	C. Edward Polk, Jr. Virginia Bar No. 43612 EXELA PHARMA SCIENCES, LLC 11710 Plaza America Drive, Suite 2000 Reston, Virginia 20190 703-989-5397 (telephone) 703-729-3279 (fax) <a href="mailto:epolk@exela.us">epolk@exela.us</a>
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Attorneys for EXELA PHARMA SCIENCES, LLC; EXELA PHARMSCI, INC; and  
EXELA HOLDINGS, INC.

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## I. INTRODUCTION

In accordance with the Administrative Procedures Act (“APA”), the actions of the U.S. Patent and Trademark Office (“PTO”) must be expressly authorized by statute or other governing law. Moreover, the APA precludes PTO from acting arbitrarily and capriciously in its administrative decision-making. Here, PTO violated the APA, 5 U.S.C. § 706, by receiving, processing and reviving an abandoned international patent application contrary to the statutory standards for these actions set forth in 35 U.S.C. § 371.

Specifically, the present action concerns PTO’s improper receipt, processing and revival of the international patent application that led to issuance of U.S. Patent No. 6,992,218 (“the ‘218 patent”). During prosecution before PTO, the applicant SCR Pharmatop did not timely file the information required under 35 U.S.C. § 371(c). As a result, the international application designating the United States (hereinafter ‘218 international application or PCT/FR01/01749) did not timely enter the U.S. national stage and went abandoned under the express language of 35 U.S.C. § 371(d), which states that “[f]ailure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable.”

Despite the clear and unambiguous statutory language requiring revival of international applications designating the United States only under the stringent **unavoidable** standard, PTO received and revived SCR Pharmatop’s ‘218 international application under the less stringent **unintentional** standard. One district court has already held, under nearly identical facts, that such conduct by PTO clearly violates § 371(d).<sup>1</sup> Despite this prior ruling that was reversed on

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<sup>1</sup> See *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 491 F. Supp. 2d 916 (N.D. Cal. 2007), *rev’d on other grounds*, 543 F.3d 657 (Fed. Cir. 2008).

technical grounds, PTO defiantly continues to violate the statute. Nonetheless, several well-established canons of statutory construction support the district court's finding in *Aristocrat*, and an independent finding here that PTO violated § 371(d) by reviving the `218 international application and issuing the `218 patent.

*First*, when the words of a statute are clear and unambiguous that plain meaning controls. Here, the language of § 371(d) is clear and unambiguous that an abandoned international patent application can only be revived under the stringent "unavoidable" standard. This plain meaning compels a finding that the `218 international application was improperly received, processed and revived; and that the `218 patent never should have issued. This Court needs to look no further than this bedrock principle of statutory construction to grant summary judgment in Exela's favor.

*Second*, even if this Court looks beyond the plain meaning of § 371(d), other canons of statutory interpretation compel a finding that PTO violated § 371(d). It is well settled that a statutory provision addressing the precise issue before this Court controls any general provision in the same statute. Here, § 371(d) clearly and unambiguously addresses the precise issue before this Court, *i.e.*, under what conditions can an international application designating the United States be revived. Such an application can only be revived if the applicant shows that its failure to meet the requirements of § 371(c) "was unavoidable." This clear and unambiguous statutory text cannot be altered through resort to other, generic provisions of the Patent Act. This principle of statutory construction further compels an order granting summary judgment in Exela's favor.

*Third*, a statute cannot be interpreted to render any of its provisions meaningless. This is another well-established canon of statutory interpretation. Here, adopting PTO's position that an international application can be revived under the lesser unintentional standard renders § 371(d) meaningless. Congress clearly and unambiguously decided that international patent applications

can only be revived under the stringent “unavoidable” standard. Interpreting § 371(d) to include both unavoidable and unintentional delays renders the statutory text chosen by Congress superfluous. This principle of statutory construction further compels an order granting summary judgment in Exela’s favor.

*Finally*, beyond PTO’s clear statutory violation, PTO’s revival of the `218 international application and issuance of the `218 patent was a clear violation of Article I, § 8 of the U.S. Constitution. Once abandoned, any invention disclosed in PCT/FR01/01749 passed into the public domain (37 C.F.R. § 1.495) and became free for all to exploit in the United States. *Pennock v. Dialogue*, 27 U.S. 1, 16 (1829). Because the Constitution prevents patenting of information already in the public domain, Congress chose an extremely tough standard for revival of abandoned international applications. This choice strikes a balance between the American public’s right to use information already in the public domain and protection of foreign inventors when their information passes into the public domain through no real fault of their own. PTO’s restructuring of this balance through use of the lesser unintentional standard violates Article I, § 8 of the U.S. Constitution by basically allowing a foreign inventor to recapture its abandoned subject matter “at his pleasure,” which the Supreme Court has held violates the U.S. Constitution. *Id.* (“This inchoate right, thus once gone, cannot afterwards be resumed at his pleasure; for, where gifts are once made to the public in this way, they become absolute. Thus, if a man dedicates a way, or other easement to the public, it is supposed to carry with it a permanent right of user.”).

For each of these reasons standing alone, PTO’s revival of the `218 international application and subsequent issuance of the `218 patent must be declared arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under 5 U.S.C. § 706(2)(A);



contrary to constitutional right, power, privilege or immunity under § 706(2)(B); and in excess of statutory authority and limitation, or short of statutory right under § 706(2)(C). Accordingly, summary judgment should be entered in Exela's favor.

## **II. STATEMENT OF UNDISPUTED MATERIAL FACTS<sup>2</sup>**

On June 6, 2000, SCR Pharmatop filed French patent application FR 00 07231.<sup>3</sup> One year later, on June 6, 2001, SCR Pharmatop filed in the United States, under the Patent Cooperation Treaty ("PCT"), international patent application number PCT/ FR01/01749, which claimed priority to FR 00 07231.<sup>4</sup>

The deadline to enter the national stage in the United States for PCT/FR01/01749 was thirty months from June 6, 2001 or December 6, 2002. As such, to avoid abandonment of PCT/FR01/01749, SCR Pharmatop needed to submit a copy of the international application and the basic national fee by December 6, 2002. SCR Pharmatop failed to comply with either requirement.<sup>5</sup> Therefore, PCT/FR01/01749 did not enter the U.S. national stage within the 30-month statutory deadline and became abandoned.<sup>6</sup> Once abandoned, any invention disclosed in PCT/FR01/01749 passed into the public domain and became free for anyone to exploit in the United States.

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<sup>2</sup> The Administrative Record filed by PTO is cited as A \_\_\_\_\_. PTO's Memorandum of Law supporting its Motion to Dismiss is cited as PTO MTD Brief \_\_\_\_\_.

<sup>3</sup> A205; PTO MTD Br. at 6.

<sup>4</sup> A205; PTO MTD Br. at 6.

<sup>5</sup> See A15; A219; PTO MTD Br. at 7 ("SCR failed, however, to make the required submissions by that date, and the application became abandoned.").

<sup>6</sup> A219-20.

On January 2, 2003, nearly a month after the statutory 30-month deadline had already lapsed, SCR Pharmatop petitioned PTO to revive PCT/FR01/01749 stating that the delay in meeting the §371(c) requirements was merely “unintentional.”<sup>7</sup> PTO granted the petition to revive on or about April 25, 2003.<sup>8</sup> PTO subsequently forwarded the application to the National Stage Processing Branch of the PCT Operations for continued processing.<sup>9</sup> The national stage application was assigned U.S. patent application number 10/332,060, which issued on January 31, 2006 as the `218 Patent.

On or about August 18, 2011, Intervenor SCR Pharmatop and Cadence Pharmaceuticals, Inc. sued Exela in the U.S. District Court for the District of Delaware for infringement of the `218 patent.

### **III. ARGUMENT**

PTO’s receipt and processing of U.S. national stage application 10/332,060 and its revival of PCT/FR01/01749 (A) violated the Patent Act because Congress has not authorized PTO to revive international applications designating the United States under the lesser unintentional standard and (B) violated the U.S. Constitution because PTO improperly removed information from the public domain. Specifically, PTO is authorized to receive and process international applications designating the United States after abandonment only when the applicant shows its delay in meeting the statutory requirements was unavoidable. Given that PTO has no authority to add rights not granted by Congress, PTO’s revival of the `218 international application under the lesser unintentional standard exceeded its statutory authority.

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<sup>7</sup> A15; A219-20; PTO MTD Br. at 6-7.

<sup>8</sup> A15.

<sup>9</sup> A15.

Also, the U.S. Supreme Court has declared, in clear and certain terms, that removal of knowledge that passes into the public domain is beyond the power of Congress (and certainly beyond the power of PTO). Indeed, once information passes into the public domain, it becomes free for all to exploit. Given this Constitutional mandate, Congress has allowed for receipt of abandoned international applications, and thus withdrawal of information that has already passed into the public domain, only when some event beyond control of the foreign applicant has caused its invention to pass into the public domain. Congress achieved this goal through use of the stringent unavoidable standard. Use of the stringent unavoidable standard comports with the Supreme Court's holding in *Pennock v. Dialogue* that "[t]his inchoate right, thus once gone, cannot afterwards be resumed at his pleasure; for, where gifts are once made to the public in this way, they become absolute."<sup>10</sup> PTO's attempt to readjust this balance through use of the lesser unintentional standard deviates from this holding and the Constitutional mandate of promoting the progress of science and, thus, violates the U.S. Constitution.

For these reasons, which are discussed in more detail below, PTO's revival of the abandoned '218 international application and issuance of the '218 patent was beyond PTO's statutory authority and unconstitutional. Summary judgment should be entered in favor of Exela and the '218 patent declared null and void.

**A. PTO's Revival of the '218 International Application Exceeded its Statutory Authority**

PTO has no substantive rulemaking authority and its strained interpretation of § 371(d) is entitled to no deference from this Court. *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes

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<sup>10</sup> *Pennock*, 27 U.S. at 16.

beyond the meaning that the statute can bear.”). In this regard, the Federal Circuit has explained that:

As we have previously held, the broadest of the PTO’s rulemaking powers — 35 U.S.C. § 6(a) — authorizes the Commissioner to promulgate regulations directed only to “the conduct of proceedings in the [PTO]”; it does NOT grant the Commissioner the authority to issue substantive rules. . . . Because Congress has not vested the Commissioner with any general substantive rulemaking power, the “Final Determination” at issue in this case cannot possibly have the “force and effect of law.” . . . Thus, the rule of controlling deference set forth in *Chevron* does not apply. Such deference as we owe to the PTO’s interpretive “Final Determination” . . . arises, not from the rule of *Chevron*, but solely from, *inter alia*, the thoroughness of its consideration and the validity of its reasoning, *i.e.*, its basic power to persuade if lacking power to control.<sup>11</sup>

Given PTO’s lack of rulemaking authority, PTO must act within the statutory framework enacted by Congress. In 35 U.S.C. § 371(d), Congress enacted a clear and unambiguous procedure for reviving abandoned international patent applications. Specifically, Congress authorized only one process for reviving such applications when it declared that:

Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable.

35 U.S.C. § 371(d).

To revive the `218 international application, PTO had to work within this statutory framework. As is clearly evident from the statutory text, however, PTO had no authority to revive PCT/FR01/01749 under the lesser unintentional standard. The clear and unambiguous language of § 371(d) compels this conclusion.

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<sup>11</sup> *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (internal citations omitted) (emphasis added).

**1. 35 USC § 371(d) is clear and unambiguous in requiring unavoidable delay for reviving international applications**

Section 371(d) of the Patent Act provides a detailed procedure for reviving international patent applications. The relevant text of 35 U.S.C. § 371(d) reads as follows:

The requirements with respect to the national fee referred to in subsection (c)(1), the translation referred to in subsection (c)(2), and the oath or declaration referred to in subsection (c)(4) of this section shall be complied with by the date of the commencement of the national stage or by such later time as may be fixed by the Director. The copy of the international application referred to in subsection (c)(2) shall be submitted by the date of the commencement of the national stage. **Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable.**

35 U.S.C. § 371(d) (emphasis added).

The statutory text set forth above is clear and unambiguous. Failure of an applicant to comply with the requirements of § 371(c) **shall** result in abandonment of an international patent application unless the applicant can demonstrate **unavoidable** delay. Where, as here, the statutory language is clear, this Court's sole function is enforcing the statute according to its terms. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980) ("We begin with the familiar canon of statutory construction that the starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive."). This point of law has been settled for nearly a century.<sup>12</sup> Indeed, "[w]here the language is plain and admits of no more than one meaning, the duty of interpretation does not arise, and the rules which are to aid doubtful

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<sup>12</sup> *Caminetti v. United States*, 242 U.S. 470, 485 (1917) ("[T]he meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, and if the law is within the constitutional authority of the lawmaking body which passed it, **the sole function of the courts is to enforce it according to its terms.**") (emphasis added).

meanings need no discussion.” *Caminetti*, 242 U.S. at 485. This is the penultimate rule of statutory construction in Supreme Court, Fourth Circuit, and Federal Circuit case authority.<sup>13</sup>

Here, the language of § 371(d) is clear and unambiguous and amenable to only one construction. International applications cannot be revived under the **unintentional** standard because Congress has declared that such application can only be revived if “it be shown to the satisfaction of the Director that such failure to comply was **unavoidable**.” Try as they may, PTO and Intervenor can create no ambiguity in this statutory language.

Where Congress uses “shall” it is ordinarily a command. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) (“Use of the word ‘shall’ in a statute generally denotes the imperative.”).<sup>14</sup> Congress provided one and only one pathway for reviving abandoned international applications, *i.e.*, a showing that failure to comply with the statutory requirements was unavoidable. “A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” *Perrin v. United States*, 444 U.S. 37, 42 (1979). This Court must “look to the ordinary meaning of [unavoidable delay] at the time Congress enacted the statute.” *Id.*

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<sup>13</sup> See, e.g., *Rubin v. United States*, 449 U.S. 424, 430 (1981) (“When we find the terms of a statute unambiguous, judicial inquiry is complete, except ‘in rare and exceptional circumstances.’”) (quotation omitted); *Hillman v. IRS*, 263 F.3d 338, 342 (4th Cir. 2001) (“The general rule is that unless there is some ambiguity in the language of a statute, a court’s analysis must end with the statute’s plain language (the Plain Meaning Rule.)”); *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395 (Fed. Cir. 1990) (“‘When . . . the terms of a statute [are] unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances.’ . . . Moreover, absent a ‘clearly expressed legislative intention to the contrary,’ a statute’s plain meaning ‘must ordinarily be regarded as conclusive.’”).

<sup>14</sup> See also *BlackLight Power, Inc. v. Rogan*, 295 F.3d 1269, 1273 (Fed. Cir. 2002) (stating that the word “shall” imposes a duty); *Grav v. United States*, 886 F.2d 1305, 1307-08 (Fed. Cir. 1989) (holding that use of the word “shall” indicates the action is mandatory).

When Congress enacted § 371(d) in 1984, “unavoidable” delay had a firmly established meaning distinct from unintentional delay.<sup>15</sup> *See, e.g.*, Manual of Patent Examination of Procedure (MPEP) § 711.03 (5th ed. 1983) (describing the unintentional delay standard as “substantially less vigorous than the standard applied for unavoidable delay petitions”). PTO’s own rules make that point equally clear today. *See, e.g.*, MPEP § 711.03 (8th ed., 9th rev., Aug. 2012) (“‘[U]navoidable’ delay and ‘unintentional’ delay are not alternatives.”). As PTO and Intervenor must concede, when Congress enacted § 371(d) unavoidable delay and unintentional delay had very different meanings. In PTO’s own words, they “are not alternatives.” *Id.*

This conclusion is consistent with the finding of at least one district court, which held under nearly identical facts, that there is no ambiguity in the text of § 371(d):

**Here, the plain language of Section 133 and 371(d) is clear and unambiguous.** Both statutes explicitly prescribe that a patent application “shall be regarded” as abandoned unless it can be shown that the delay was “unavoidable.” 35 U.S.C. §§ 133, 371(d). Neither section references an “unintentional” standard. In turning to Congress’s use of the terms, “unavoidable” and “unintentional” delay, it is evident that Congress intended a distinction between the “unavoidable” and “unintentional” standards. . . . **Congress’s deliberate use of, and distinction between, the terms, “unintentional” and “unavoidable,” within Title 35 is evidence that Congress has created different standards in evaluating certain delays on the part of a patentee.** Based on the express language of the statutes at issue, the Court finds clear support on their face that the “unavoidable” standard governs the review of delays under . . . Section 371(d).

*Aristocrat*, 491 F. Supp. 2d at 925-26 (emphasis added).

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<sup>15</sup> Unintentional delay typically requires a mere statement from the applicant that the delay in filing the required information was “unintentional.” PTO typically does not require any justification for this statement. Unavoidable delay, however, uses a reasonably prudent person standard to determine, based upon a detailed showing by the applicant, whether the recalcitrant party “exercised the care or diligence used by prudent and careful people in relation to their most important business [matters].” *Kim v. Quigg*, 718 F. Supp. 1280, 1284 (E.D. Va. 1989). The unavoidable delay standard was intended by Congress to be “strict.” *Burandt v. Dudas*, 496 F. Supp. 2d 643, 649 (E.D. Va. 2007).

The *Aristocrat* district court also analyzed the legislative history and evolution of § 371(d) and found that this evidence further supported its conclusion that unavoidable delay is the only standard allowed for reviving international patent applications:

Next, turning to Section 371, the legislative history similarly reveals no Congressional intent to import an “unintentional” standard therein. As originally enacted in 1975, Section 371 did not provide any mechanism to excuse abandonment whatsoever. *See* Pub.L. 94-131 (Nov. 14, 1975). In 1984, after the enactment of Section 41(a)(7) – which referenced the concept of “unintentional” delay – Congress amended Section 371 to excuse abandonment, only if the delay was “unavoidable.” *See* Pub.L. 98-622 (Nov. 8, 1984). Thus, despite the opportunity to include or otherwise reference an “unintentional” standard within Section 371, Congress has refrained from doing so. Accordingly, Court finds additional support in the legislative history of the statutes at issue that the “unavoidable” standard governs the review of delays under . . . Section 371(d).

*Id.* at 926.

The court’s analysis of § 371(d) in *Aristocrat* is compelling. The concept of unavoidable delay as a basis for reviving abandoned patent applications has been part of the Patent Act since 1861. *Id.* When originally enacted in 1975, however, § 371 provided no mechanism for reviving abandoned international patent applications, despite revival being available for U.S. patent applications under 35 U.S.C. § 133. *Id.*

In 1984, Congress added § 371(d) to excuse abandonment of international patent applications, but only under the “unavoidable” standard. Since then, section 371 has been revised at least eight times by Congress. But, not once, has Congress allowed for revival of international patent applications under the lesser unintentional standard. Based upon this history, the *Aristocrat* court held that:

Congress’s failure to amend Section 371 to include the unintentional standard, allows an inference that Congress’s intended revival under Section 371 to be governed by the “unavoidable” standard only. If Congress had truly intended for Section 371 . . . to encompass the ‘unintentional’ standard, it would have amended them as it did with Section 111.

*Id.* at 928 n.14.



Given the lack of any ambiguity in § 371(d), this Court must construe the statutory language to mean exactly what it says. International patent applications can only be revived under the unavoidable standard. Accordingly, PTO's decision to revive PCT/FR01/01749 under the lesser unintentional standard simply cannot be reconciled with the statutory text. For this reason standing alone summary judgment should be entered in Exela's favor. *Rubin*, 449 U.S. at 430 ("When we find the terms of a statute unambiguous, judicial inquiry is complete, except 'in rare and exceptional circumstances.'").

## **2. Several Other Canons of Statutory Construction Compel the Grant of Summary Judgment to Exela**

Even if this Court goes beyond the clear and unambiguous language of § 371(d), several additional canons of statutory construction compel grant of summary judgment in Exela's favor. *First*, it is well-settled that the specific language of § 371(d) trumps any general authority found elsewhere in the Patent Act. *Second*, § 371(d) cannot be interpreted, as PTO and Intervenor undoubtedly will request, to render any portions of this statutory provision meaningless.

### **a) The Specific Language of § 371(d) Controls Over Any General Revival Authority in the Patent Act**

It is well-settled that a statute directed to the precise issue before the Court controls over general provisions of the same statute. As the Supreme Court held over a century ago:

It is an old and familiar rule that, "where there is, in the same statute, a particular enactment, and also a general one, which, in its most comprehensive sense, would include what is embraced in the former, the particular enactment must be operative, and the general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment." . . . This rule applies wherever an act contains general provisions and also special ones upon a subject, which, standing alone, the general provisions would include.<sup>16</sup>

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<sup>16</sup> *United States v. Chase*, 135 U.S. 255, 260 (1890).

PTO does not dispute, and indeed cannot reasonably dispute, that SCR Pharmatop failed to meet any of the requirements of § 371(c) by the 30-month deadline. And, consequently, PTO and Intervenor must concede that PCT/FR01/01749 failed to enter the national stage by the 30-month statutory deadline. The only material issue in dispute is whether PTO possessed authority to receive and revive PCT/FR01/01749 under the lesser unintentional standard. This issue is squarely addressed by § 371(d). PTO and Intervenor cannot reasonably argue otherwise.

PTO and Intervenor undoubtedly will ask this Court to look to some general provision of the Patent Act to avoid the clear and negative consequences of § 371(d) to their positions in this case. However, looking to general provisions of the Patent Act to avoid § 371(d) violates an elementary principle of statutory construction holding that specific statutory provisions govern general provisions. Thus, even if PTO and Intervenor could identify some general authority from other provisions of the Patent Act, precedents of the Supreme Court, Fourth Circuit and Federal Circuit uniformly hold that the specific provisions of § 371(d) control the relevant inquiry in this case.<sup>17</sup> For this reason, standing alone, summary judgment should be entered in Exela's favor.

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<sup>17</sup> See, e.g., *Guidry v. Sheet Metal Workers Nat'l Pension Fund*, 493 U.S. 365, 375-76 (1990) ("It is an elementary tenet of statutory construction that '[w]here there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one'" (alteration in original)); *Warren v. N.C. Dep't of Human Res.*, 65 F.3d 385, 390 (4th Cir. 1995) ("Indeed, it is an elementary principle of statutory construction that a specific statutory provision controls a more general one."); *Thiess v. Witt*, 100 F.3d 915, 919 (Fed. Cir. 1996) ("It is a standard rule of construction that 'a specific statute controls over a general one 'without regard to priority of enactment.'")

**b) Construing 35 U.S.C. § 371(d) to include unintentional delay renders the statutory language chosen by Congress meaningless**

Another “elementary canon of [statutory] construction” is that a statute “should be interpreted so as not to render one part inoperative.”<sup>18</sup> Congress expressed its clear and unambiguous intent when it enacted § 371(d). The imperative “shall” is a command that directs PTO to require those applicants failing to comply with § 371(c) to make a showing of unavoidable delay. Holding otherwise based on generic provisions of the Patent Act renders § 371(d) superfluous. As the Supreme Court explained:

The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission. To eliminate the contradiction, the specific provision is construed as an exception to the general one. But the canon has full application as well to statutes such as the one here, in which a general authorization and a more limited, specific authorization exists side-by-side. There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one, “violat[ing] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute.”<sup>19</sup>

Thus, even if PTO is authorized to revive certain domestic applications under a lesser unintentional standard, that authorization did not extend to PCT/FR01/01749. Indeed, holding that § 371(d) is superseded by other general provisions of the Patent Act would “violat[e] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute” because §

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<sup>18</sup> *Colautti v. Franklin*, 439 U.S. 379, 392 (1979).

<sup>19</sup> *RadLAX Gateway Hotel, LLC. v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (alteration in original) (citations omitted).

371(d) would be rendered meaningless by the interpretation espoused by PTO.<sup>20</sup> Such an interpretation is not supported by Supreme Court, Fourth Circuit, or Federal Circuit precedent.<sup>21</sup>

Courts are not empowered to rewrite statutes. *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 376 (1986) (“As we so often admonish, only Congress can rewrite this statute.”).

Accordingly, § 371(d) must be interpreted to mean exactly what it says by requiring that international patent applications be revived only under the unavoidable delay standard.

Otherwise, this Court will render the statutory text chosen by Congress superfluous and contravene several tenants of statutory construction.

\* \* \*

In sum, enforcing § 371(d) according to its clear and unambiguous terms and adding no remedies beyond those specifically authorized by Congress leads to only one conclusion. PTO had no statutory authority to revive PCT/FR01/01749 under the unintentional standard and, thus, no authority to issue the `218 patent. Furthermore, PTO’s clear violation of § 371(d) has caused severe prejudice to Exela. The patent owner, SCR Pharmatop, and a U.S. licensee, Cadence Pharmaceuticals, are currently enforcing the `218 patent against Exela in district court litigation. *See Cadence Pharms. Inc. v. Paddock Labs.*, No. 11-00733-LPS (D. Del. filed Aug. 18, 2011). But for PTO’s improper conduct, the `218 patent could not be asserted against Exela. As such,

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<sup>20</sup> *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932).

<sup>21</sup> *See, e.g., United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (“‘The cardinal principle of statutory construction is to save and not to destroy.’ It is our duty ‘to give effect, if possible, to every clause and word of a statute’ rather than to emasculate an entire section, as the Government’s interpretation requires.”) (internal citations omitted); *United States v. Johnson*, 325 F.3d 205, 209 (4th Cir. 2003); *Roche v. Merit Sys. Prot. Bd.*, 596 F.3d 1375, 1380 (Fed. Cir. 2010).

the '218 patent should be declared null and void and summary judgment entered in Exela's favor.

**B. PTO's Revival of the '218 International Application and Issuance of the '218 Patent Was Unconstitutional**

*Finally*, Congress and not PTO is charged under the Constitution with striking the proper balance between incentivizing inventors through patent grants and protecting rights of the public to use what is in the public domain. As the Supreme Court has explained:

Article I, § 8, cl. 8, of the Constitution gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the “Progress of Science and useful Arts.” As we have noted in the past, the Clause contains both a grant of power and certain limitations upon the exercise of that power.<sup>22</sup>

The Supreme Court has further explained that “[t]he federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.”<sup>23</sup> Once Congress enacts legislation it deems appropriate under its patent authority, it becomes PTO's “duty” to enforce these policy choices as enacted by Congress. PTO cannot pick and choose which enactments it prefers to follow:

Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. *Gibbons v. Ogden*, 9 Wheat. 1. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. *McClurg v. Kingsland*, 1 How. 202, 206. **It is the duty of the Commissioner of Patents and of the courts in the administration of the**

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<sup>22</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

<sup>23</sup> *Id.* at 150-51.

**patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.**<sup>24</sup>

Here, Congress expressly stated that for an international application to be received by PTO and revived beyond the 30-month deadline, PTO must find a showing of unavoidable delay. 35 U.S.C. § 371(d). PTO had no discretion to revive PCT/FR01/01749 under a lesser showing. Whatever PTO's reasoning for doing so, its blatant disregard of § 371(d) recalibrates the "careful" balance that Congress struck between the rights of the public and the rights of foreign inventors.<sup>25</sup> Although the legislative history is largely silent on its reasoning, Congress obviously desired a heightened revival standard for international applications. *Cf. Burandt*, 496 F. Supp. 2d at 649 ("Congress intended the 'unavoidable' delay standard to be strict."). Indeed, prior to enactment of § 371(d), international patent applications could not be revived at all.

Moreover, if Congress felt the need to do so, it had multiple opportunities to amend 35 USC § 371 and "rebalance" the revival standards for international applications. As noted above, the legislative history shows that § 371 has been revised at least eight times since its enactment in 1975. But, not once, has Congress allowed for revival of international applications under the lesser unintentional standard.

By allowing foreign inventors to utilize the less stringent "unintentional" standard, patent applications that would otherwise be abandoned have been impermissibly revived and issued as patents by PTO. This conduct by PTO removes information from the public domain in a manner not authorized by Congress. This was a violation of the U.S. Constitution and a violation of

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<sup>24</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) (emphasis added).

<sup>25</sup> As the Supreme Court explained, "[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats*, 489 U.S. at 146.

Federal law which “requires[] that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent.”<sup>26</sup> Summary judgment should be granted in Exela’s favor for this reason standing alone.

#### IV. CONCLUSION

For the reasons stated herein, Exela’s motion for summary judgment should be granted.

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*Of counsel*  
Satish Chintapalli  
EXELA PHARMA SCIENCES, LLC  
1325 William White Pl, NE  
Lenoir, NC 28645  
828-758-5474 (telephone)  
828-757-7888 (fax)  
*satish@exela.us*

Respectfully submitted,

/s/

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C. Edward Polk, Jr.  
Virginia Bar No. 43612  
EXELA PHARMA SCIENCES, LLC  
11710 Plaza America Drive, Suite 2000  
Reston, Virginia 20190  
703-989-5397 (telephone)  
703-729-3279 (fax)  
*epolk@exela.us*

*Attorney for Plaintiffs Exela Pharma  
Sciences, LLC, Exela PharmSci, Inc. and Exela  
Holdings, Inc.*

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<sup>26</sup> *Lear, Inc. v. Adkins*, 395 U.S. 653, 668 (1969).

### CERTIFICATE OF SERVICE

I hereby certify that on the 16th day of October , 2012, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

Dennis Carl Barghaan, Jr Assistant United States Attorney 2100 Jamieson Avenue Alexandria, Virginia 22314 (703) 299-3891(direct) (703) 299-3983 (fax) dennis.barghaan@usdoj.gov	Peter Thomas Ewald Oliff & Berridge, PLC 277 South Washington Street Suite 500 Alexandria, Virginia 22314 Telephone: (703) 836-6400 Facsimile: (703) 836-2787 Email: pewald@oliff.com
Stephen Obermeier Assistant United States Attorney 2100 Jamieson Avenue Alexandria, Virginia 22314 (703) 299-3785 (direct) (703) 299-3983 (fax) stephen.obermeier@usdoj.gov	Aaron Levi Webb Oliff & Berridge, PLC 277 South Washington Street Suite 500 Alexandria, Virginia 22314 Telephone: (703) 836-6400 Facsimile: (703) 836-2787 Email: awebb@oliff.com

/s/

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C. Edward Polk, Jr.  
Virginia Bar No. 43612  
EXELA PHARMA SCIENCES, LLC  
11710 Plaza America Drive, Suite 2000  
Reston, Virginia 20190  
703-989-5397 (telephone)  
703-729-3279 (fax)  
epolk@exela.us

*Attorney for Plaintiffs Exela Pharma  
Sciences, LLC, Exela PharmSci, Inc. and Exela  
Holdings, Inc.*